IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,	)	
Plaintiffs,	)	C.A. No. 12-1032-GMS
v.	)	
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,	)	
Defendants.	)	

DEFENDANTS WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, AND WARNER CHILCOTT PLC'S ANSWERING CLAIM CONSTRUCTION BRIEF

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TABLE OF CONTENTS

I. If Warner Chilcott's Constructions Are Not Adopted, the Vague, Subjective, and Relative Terms of the "Whereby" Clause Have No Definite Meaning 1

A. Bayer's proposed constructions are unsupported and indefinite. 2

1. "high contraceptive reliability" 4

2. "low incidence of follicular development" 6

3. "satisfactory cycle control"/"reliable avoidance of intracyclic menstrual bleeding" 7

4. "reliable avoidance" of undesirable side effects 10

B. Bayer's attacks on Warner Chilcott's constructions are meritless 11

II. Bayer's Construction of "Effective Estrogen Content" Is Erroneous 14

III. The Court Should Adopt Warner Chilcott's Construction of "Between These Two Hormone Components" 15

TABLE OF AUTHORITIES

Page(s)

CASES

Chef Am., Inc. v. Lamb-Weston, Inc.,
358 F.3d 1371 (Fed. Cir. 2004).....12

Computer Docking Station Corp. v. Dell, Inc.,
519 F.3d 1366 (Fed. Cir. 2008).....11, 12

Datamize, LLC v. Plumtree Software, Inc.,
417 F.3d 1342 (Fed. Cir. 2005)..... *passim*

Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,
93 F.3d 1572 (Fed. Cir. 1996).....14

Honeywell v. Int'l Trade Comm'n,
341 F.3d 1332 (Fed. Cir. 2003).....6, 10

Light Guard Sys., Inc. v. Spot Devices, Inc.,
No. 3:10-CV-0737-LRH-RAM, 2012 WL 2131943
(D. Nev. June 12, 2012).....1

Nautilus, Inc. v. Biosig Instruments, Inc.,
134 S. Ct. 2120 (2014).....4

Norian Corp. v. Stryker Corp.,
432 F.3d 1356 (Fed. Cir. 2005).....12

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005).....11

Rheox, Inc. v. Entact, Inc.,
276 F.3d 1319 (Fed. Cir. 2002).....12

Seachange Intern., Inc. v. C-COR, Inc.,
413 F.3d 1361 (Fed. Cir. 2005).....12

SuperGuide Corp. v. DirecTV Enterprises, Inc.,
358 F.3d 870 (Fed. Cir. 2004).....11

In obtaining the '940 patent, the inventors represented that their oral contraceptive outperformed the prior art. Bayer's opening brief (D.I. 61) is a classic, albeit futile, "nose of wax" attempt to escape the consequences of those representations. Equally important, Bayer invites the Court to adopt indefinite constructions that have no support in the intrinsic evidence. The Court should reject Bayer's proposals, and adopt Warner Chilcott's constructions.

I. If Warner Chilcott's Constructions Are Not Adopted, the Vague, Subjective, and Relative Terms of the "Whereby" Clause Have No Definite Meaning

The parties disagree about the meaning of five relative, subjective claim terms in the "whereby" clause of claim 1 of the '940 patent: "*high* contraceptive reliability"; "*low* incidence of follicular development"; "*satisfactory* cycle control"; "*reliable* avoidance of intracyclic menstrual bleeding"; and "*reliable* avoidance of . . . undesirable side effects."[1] By themselves, these imprecise terms do not have sufficient clarity to delineate the scope of the claims. *See* Warner Chilcott Opening Brief (D.I. 62) at 7-16. Absent more guidance, a person of ordinary skill in the art ("POSA") would not have known how "high" an oral contraceptive's reliability had to be to satisfy the claims' requirement of "high" contraceptive reliability; how "low" the incidence of follicular development needed to be; how good the cycle control needed to be considered "satisfactory"; or what "reliable" avoidance meant. *Id.*

When, as here, claims contain subjective or relative terms of degree, the Court must look to the specification and prosecution history for an "objective standard" against which to assess the meaning of those terms. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348,

[1] There is no basis for Bayer's attempt to conflate these distinct terms into a single limitation. D.I. 61 (Bayer Br.) at 8. Bayer's sole "support" for its proposal – which would leave unclear whether and to what extent each separate requirement needed to be satisfied in an infringement analysis – is a single off-point, out-of-jurisdiction decision from Nevada that has nothing to do with oral contraceptives. *Id.* (citing *Light Guard Sys., Inc. v. Spot Devices, Inc.*, No. 3:10-CV-0737-LRH-RAM, 2012 WL 2131943 at *7 (D. Nev. June 12, 2012)). The Court should reject Bayer's proposal.

1350-53 (Fed. Cir. 2005); Warner Chilcott Opening Brief (D.I. 62) at 8. As explained in Warner Chilcott's opening brief, the "objective standard" here – if there is any standard – is the prior art. *Id*. In overcoming an obviousness rejection, the applicants *specifically added* the disputed terms to the claims, explained that the prior art *lacked* the characteristics embodied by these terms, and argued that the presence of such characteristics in their regimen warranted a patent:

> There is no teaching in the cited prior art . . . whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. ***The present invention provided such a low-dose, contraceptively effective pharmaceutical preparation for the first time***. '940 Patent File History at BHC-LOLO-00000091 (Jan. 20, 1999 Amendment at 5).

See also id. at BHC-LOLO-00000018-21; '940 patent, 6:9-39 (listing six advantages of the invention over "the previously described [prior art oral contraceptive] preparations").

Consistent with this intrinsic evidence, and following the legal standard set forth in *Datamize*, Warner Chilcott proposes that the relative, subjective terms of the whereby clause should be construed against the prior art, to reflect the inventors' representations that the '940 patent outperformed the prior art with respect to each of the characteristics in the whereby clause. Warner Chilcott Opening Brief (D.I. 62) at 5-6. Absent Warner Chilcott's proposal, these subjective terms would have no definite meaning, because neither the plain language of these terms, nor Bayer's deeply flawed constructions, provides a coherent objective standard against which to assess the meaning of the disputed terms.

A. Bayer's proposed constructions are unsupported and indefinite.

Rather than defining the imprecise, subjective, relative words at the heart of the dispute – "high," "low," "satisfactory," and "reliable" – Bayer's constructions merely *repeat* these words. The only difference between Bayer's constructions and the claim terms themselves is that Bayer

has appended to each term the undefined phase "as compared to a population of healthy women not using hormonal birth control." But tacking on such an ambiguous phrase is erroneous.

First, there is no basis for adding such a phrase to the disputed terms. Neither the specification nor the prosecution history anywhere *mentions* "a population of healthy women not using hormonal birth control," let alone suggests using such a population as an objective standard against which to assess the meaning of the relative, subjective terms in the claims. *See generally* '940 patent. Bayer's proposal is nothing more than a post-hoc, attorney-manufactured attempt to evade the evidence that actually exists in the intrinsic record, not an attempt to be consistent with it.

Second, tacking on such a phrase would confound, not clarify, the scope of the claims. Bayer itself appears confused about the meaning of its "healthy population of women" phrase, using that phrase to mean different things for different terms. *See, e.g.*, D.I. 61 (Bayer Br.) at 14,15 (using the phrase to mean "the normal menstrual cycle" in connection with the "low incidence of follicular development" term, while using the phrase to mean other, undefined methods of contraception in connection with the "high contraceptive reliability" term). Bayer's construction also leaves unclear *who* the so-called population of women consists of, and *how* the "contraceptive reliability," "follicular development," "cycle control," and "side effects" must "compare" to the so-called "population of healthy women" for an oral contraceptive to satisfy the claims. Warner Chilcott Opening Brief (D.I. 62) at 10-11. For example, *how* must the contraceptive reliability of a regimen "compare" to a "population of healthy women not using hormonal birth control" to be said to have "high" contraceptive reliability? Bayer's construction leaves this question, and bevy of other similar questions, unanswered. Thus, Bayer's constructions, like the indefinite "aesthetically pleasing" term in *Datamize*, "depend solely on the unrestrained, subjective opinion of a particular individual." 417 F.3d at 1350, 1352. And they run

afoul of the Supreme Court's recent observation that "a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). That Bayer's constructions are indefinite is further reason to reject them. Warner Chilcott Opening Brief (D.I. 62) at 10-11. Additional flaws with each of Bayer's constructions are discussed below.

1. "high contraceptive reliability"

Bayer is wrong to suggest that, by itself, the term "high contraceptive reliability" has a precise, singular, commonly understood meaning that would give a person reasonable notice of the scope of the claims. *See* D.I. 61 (Bayer Br.) at 13. It does not. *See* Warner Chilcott Opening Brief (D.I. 62) at 10-11; Simon Responsive Decl. ¶¶ 3-4. Tellingly, Bayer nowhere articulates what this singular, commonly understood standard of "high" contraceptive reliability supposedly was. And the evidence Bayer cites proves that "high" reliability meant different things to different people. For instance, the Ehrlich '023 patent claimed to have "high" reliability, *see* D.I. 61 (Bayer Br.), Ex. 2 at 3:36-39, yet the '940 patent applicants argued the opposite, contrasting *their* regimen's ability to provide, *for the first time*, "high" reliability with their assertion that Ehrlich failed to do so. Jan. 20, 1999 Amendment at 5. Clearly, to the '940 applicants, Ehrlich's level of reliability was not "high." "High" in the context of the '940 patent must clearly be higher than the level of reliability found in the Ehrlich '023 patent.

In addition, Bayer has no credible basis for its contention that a person would assess "high contraceptive reliability" in comparison to a population of healthy women. D.I. 61 (Bayer Br.) at 13-14. Bayer's sole "support" is extrinsic evidence in the form of a 1998 book chapter containing a table listing average failure rates for different classes of contraceptives. *Id.* at 14 (citing Carr et al., *Textbook of Reproductive Medicine*, 708, 716-718 (2d ed. 1998)). But that extrinsic evidence does not set (or purport to set) a threshold for "high contraceptive reliability,"

or state that "high contraceptive reliability" should be assessed in relation to a population of healthy women not using hormonal birth control. D.I. 61 (Bayer Br.), Ex.5; Simon Responsive Decl. ¶¶ 6-9. Even if the table did, it would conflict with the intrinsic evidence where the inventors defined "high" contraceptive reliability in relation to prior art oral contraceptives, not a so-called "population of healthy women." Warner Chilcott Opening Brief (D.I. 62) at 5-6.

Bayer also hints that *any* oral contraceptive would have "high" contraceptive reliability, because "oral contraceptives are one of the most effective forms of reversible contraception." D.I. 61 (Bayer Br.) at 14. But that argument is undermined by the intrinsic evidence, which makes clear that all oral contraceptives *do not* provide "high" contraceptive reliability. Jan. 20, 1999 Amendment at 5 (identifying "high contraceptive reliability" as a feature distinguishing the claimed regimen from the prior art). The argument is also contradicted by extrinsic evidence: the prior art did not report that *every* oral contraceptive had "high" contraceptive reliability. *See, e.g.*, Hull et al., *Effects of Norgestimate (0.250 mg) in Combination with Ethinyl Estradiol (0.035 mg) on Cervical Mucus*, Adv. Contracept. Vol. 2 pp. 71-77 at 71 (1986) (WC_DEL_00214394-00214400) (particular OC "associated with an unacceptably high pregnancy rate"); Lammers et al., *Double-Blind Comparative Acceptability Study With Two Combined Oral Contraceptives Containing 20 mcg Ethinylestradiol Plus Desogestrel or Norethisterone Acetate, Optimizing the Estrogen Dose in Oral Contraceptives*, pp. 67-74 at 71-72 (1992) (WC_DEL_00215058-68) (reporting "relatively high incidence of unintended pregnancies" with another OC); *see also* Simon Responsive Decl. ¶ 5. And, to the extent Bayer proposes a construction of "high contraceptive reliability" that some oral contraceptives *would not* meet, Bayer's construction provides no clear standard that would allow one to distinguish oral contraceptives *with* "high" contraceptive reliability from those without it.

Finally, while Bayer argues that "contraceptive reliability" should not be measured using the Pearl Index, D.I. 61 (Bayer Br.) at 14, that was and is the prevailing measure of contraceptive reliability, and contraceptive reliability must be measured *in some fashion*. Bayer does not, and cannot, argue that the Pearl Index was not a commonly used test. And if contraceptive reliability is not measured using the Pearl Index, what test *should* be used? Bayer has no answer. Absent the Pearl Index, it would not be clear what measure should apply, creating further indefiniteness problems. *Honeywell v. Int'l Trade Comm'n*, 341 F.3d 1332, 1336 (Fed. Cir. 2003) (claim is indefinite when patent fails to identify which of multiple, potentially conflicting approaches to measuring a parameter should be used).

2. "low incidence of follicular development"

Bayer argues that "low incidence of follicular development" has "a known meaning." D.I. 61 (Bayer Br.) at 15. Tellingly, though, Bayer fails to specify what that purported "known meaning" was. Bayer cites no support for its implied assertion that, on its own, this term had a clear, singular "known meaning" of sufficient precision to adequately apprise a person of ordinary skill about the scope of the claims of the '940 patent. Nor is there any support. Warner Chilcott Opening Brief (D.I. 62) at 11-13.

Bayer argues that a POSA would assess "low" incidence of follicular development "as compared to the normal menstrual cycle." D.I. 61 (Bayer Br.) at 15. But when the '940 patent specification and prosecution history discuss the "incidence" and "frequency" of "follicular development," it is in relation to other oral contraceptives, not a "normal menstrual cycle." '940 patent, 6:9-16; Jan. 20, 1999 Amendment at 5; *see also* '129 patent at 4:41-5:23, Fig. 2. And the evidence Bayer cites does not support its construction because, *inter alia*, none of this purported evidence addresses what a "low" incidence would be or what benchmark to use in assessing a "low" incidence. *See* D.I. 61 (Bayer Br.) at 15; *see also* Simon Responsive Decl. ¶ 11.

Bayer's construction also leaves unclear what frequency of follicular development would be considered "low." Bayer's approach implies that *any* oral contraceptive will have a "low" incidence, because a "normal" menstrual cycle will always have "follicular development," and *any* oral contraceptive will suppress "follicular development" to some degree (however defined). Simon Responsive Decl. ¶ 12. But that standard could not be right, because the inventors made clear that prior art oral contraceptives *did not have* a "low incidence of follicular development." Jan. 20, 1999 Amendment at 5. And, to the extent Bayer's construction does not mean that *every* oral contraceptive would have a "low" incidence of follicular development, Bayer's construction provides no clear standard or dividing line to distinguish oral contraceptives that provide a "low" incidence of follicular development from those that do not. *Id.* ¶¶ 13-14.

Finally, Bayer misleads when stating that the inventors did not say that their regimen would achieve the "lowest level of follicular development." D.I. 61 (Bayer Br.) at 15. The inventors stated that their patented regimen provides "[a] significantly lower frequency of follicular development" than all of the prior art regimens described in the specification ('940 patent, 6:9-17) – the very crux of Warner Chilcott's construction. Similarly, the inventors represented that they provided "for the first time" a low-dose regimen with a "low incidence of follicular development." Warner Chilcott Opening Brief (D.I. 62) at 5-6.

3. "satisfactory cycle control"/"reliable avoidance of intracyclic menstrual bleeding"

These subjective terms also did not have a singular, precise meaning at the time of the invention. Simon Opening Decl. ¶¶ 18-24. In the 1995-1996 timeframe, there were not even standardized definitions used in *measuring* cycle control, much less consensus on a single, agreed upon threshold of "satisfactory" or "reliable" cycle control. Simon Responsive Decl. ¶¶ 17-18; *see also* Rosenberg, Michael J., et al., *Oral Contraceptives and Cycle Control: A Critical Review of the Literature*, Vol. 8, Supplement 1 Advances In Contraception, pp. 35-45 at 43

(1992) (WC_DEL_00036281-WC_DEL_00036292 at WC_DEL_00036290) (observing "considerable variability in the design, conduction, and reporting methods" among cycle control studies, and that "[r]esearch could be improved by adopting a standardized definition of spotting, breakthrough bleeding, and amenorrhea and with a clear definition of how data are to be collected."); *see also* Mishell, D. R. et al., *Combined Hormonal Contraceptive Trials: Variable Data Collection and Bleeding Assessment Methodologies Influence Study Outcomes and Physician Perception*, Contraception Vol. 75, pp. 4-10 (2007) (WC_DEL_00091444-50). While Bayer contends that these terms have an "understood meaning to one of skill in the art," Bayer fails to articulate a precise, agreed upon threshold of "satisfactory" and "reliable" avoidance. And Bayer's own evidence demonstrates that, because women respond differently to unscheduled bleeding, there was and is no single threshold as to what a "satisfactory" level of cycle control is. E. Weisberg, *Prescribing Oral Contraceptives*, 49 Drugs pp. 224-231 (1995) at 227; D.I. 61 (Bayer Br.) Ex. 13 at 227 ("Adolescents seem to be less tolerant of breakthrough bleeding than older women."); *see also* Akerlund et al., *Comparative Profiles of Reliability, Cycle Control and Side Effects*, Br J Obstet Gynaecol, Vol 100 No. 9, pp. 832-838, at 836-837 (1993) (WC_DEL_00214727-WC_DEL_00214735) (reporting that some women in a clinical trial found cycle control on an oral contraceptive to be "insufficient" while others wanted to continue taking the same oral contraceptive after completing the trial).

Bayer argues that "satisfactory" cycle control can be defined by reference to whether women continue taking the oral contraceptive, D.I. 61 (Bayer Br.) at 16, but that contention finds no basis in the intrinsic evidence. Even if continuation were the proper measure, that would only create more ambiguity, because some women will continue to use an oral contraceptive, while others will not, even when they experience the same degree of cycle control on the very same oral contraceptive. Simon Responsive Decl. ¶¶ 19-22. Moreover, it is unclear *what proportion of*

women would need to continue, and for what *duration*, for cycle control to be "satisfactory." *Id.* ¶¶ 20-21.

Bayer also contends that these terms should be assessed in relation to "the normal menstrual cycle," D.I. 61 (Bayer Br.) at 17, but when the specification and prosecution history discuss cycle control, it is in relation to prior art oral contraceptives, not a "normal menstrual cycle." *See, e.g.*, '940 patent, 6:9-39; Jan. 20, 1999 Amendment at 5. Extrinsic evidence cited by Bayer, including testimony from Dr. Darney, is irrelevant and does not support Bayer's construction in any event. Simon Responsive Decl. ¶¶ 23-29, 34-39. And Bayer's focus on the "normal" menstrual cycle also ignores prior art references that compared cycle control of an oral contraceptive against another. *See, e.g.*, Akerlund at 833-37 (WC_DEL_00214727-35), Lammers at 68-69 (WC_DEL_00215058-68), Masson et al., *Clinical Comparison of Two Triphasic Oral Contraceptives with Levonorgestrel or Norethindrone: A Prospective, Randomized, Single-Blind Study*, Contraception Vol. 47 pp. 43-54 at 43-44, 48-51 (1993) (WC_DEL_00397409-20); Simon Responsive Decl. ¶ 26.

Even if cycle control were appropriately measured against a "normal" menstrual cycle, Bayer's construction fails to clarify *how well* the oral contraceptive must mimic the "normal" menstrual cycle to have "satisfactory" cycle control or "reliably avoid" intracylic bleeding. Simon Responsive Decl. ¶ 29.[2] And Bayer's argument that "cycle control" should not be defined in terms of incidence of unscheduled bleeding, D.I. 61 (Bayer Br.) at 16-17, should be rejected, both because the '940 patent defines "cycle control" as "incidence of intracyclic menstrual

[2] The portions of the '940 specification cited by Bayer do not support its construction of "satisfactory" cycle control. For example, 1:51-58 (cited at D.I. 61 (Bayer Br.) at 16) equates "good cycle control" with a "low incidence of intracyclic menstrual bleeding," but does not clarify what "low" means.

bleeding,"[3] ('940 patent, 1:51-58), and because absent such a definition, "cycle control" would be indefinite, given the numerous possible ways to measure cycle control. *See, e.g. Honeywell* at 1341; Simon Opening Decl. ¶ 23.

4. "reliable avoidance" of undesirable side effects

Bayer once again cites no support for its erroneous contention that this term has "an understood meaning in the art," or explain what the meaning was. D.I. 61 (Bayer Br.) at 19; Simon Responsive Decl. ¶ 40. By itself, this subjective term is not sufficiently precise to delineate the scope of the claim.

Nor does Bayer cite intrinsic evidence supporting its contention that evaluating "reliable avoidance" involves "a comparison between women taking the oral contraceptive to women who are not taking the oral contraceptive." D.I. 61 (Bayer Br.) at 20. When the specification and prosecution history discuss side effects, they do so in relation to *other* oral contraceptives. '940 patent, 6:9-32; Jan. 20, 1999 Amendment at 5. So did other prior art. Akerlund at 836, Table 6 (WC_DEL_00214733); Cullberg et al., *Two Oral Contraceptives, Efficacy, Serum Proteins, and Lipid Metabolism*, Contraception Vol. 26, No. 3 pp. 229-243 at 236 (1982) (WC_DEL_00401577-WC_DEL_ 00401593); Corson, Stephen L., *Efficacy and Clinical Profile of a New Oral Contraceptive Containing Norgestimate*, Acta Obstetricia et Gynecologica Scandinavica Vol. 69, Supplement 152, pp. 23-31 at 28 (1990) (WC_DEL_00034707-WC_DEL_00034715); Masson at 51-52; Simon Responsive Decl. ¶ 41.

[3] Bayer contends that the inventors intended "cycle control" to mean something broader than incidence of intracyclic menstrual bleeding, citing to column 6:32-37 of the '940 patent, and arguing that this passage reveals that inventors intended that "reliable breakthrough bleeding," *i.e.*, absence of amenorrhea, should also be considered part of "cycle control." D.I. 61 (Bayer Br.) at 17. But in the very following lines, which Bayer fails to cite, the inventors distinguished "cycle control" from "low incidence of amenorrhea," ('940 patent, 6:38-39), revealing that they were not equating cycle control with lack of amenorrhea. Thus, "cycle control" should be defined in terms of "incidence of intracylic menstrual bleeding."

Bayer contends that "by definition," one would have to assess "reliable avoidance" against women not taking any contraceptives. D.I. 61 (Bayer Br.) at 20. But *by definition*, women not taking any medication do not experience *any* side effects, because side effects result from a drug or therapy. Warner Chilcott Opening Brief (D.I. 62) at 16. Thus, by definition, an oral contraceptive could not "avoid" side effects to a greater extent than healthy women not using contraception. *Id.* And Bayer leaves unclear the extent to which an oral contraceptive can increase the incidence of undesirable side effects, if at all, and still "reliably avoid" side effects. Simon Responsive Decl. ¶ 46.

B. Bayer's attacks on Warner Chilcott's constructions are meritless.

Bayer challenges Warner Chilcott's constructions primarily on the theory that Warner Chilcott's constructions are inconsistent with the terms' plain and ordinary meaning, and that the court should ignore the intrinsic evidence, contrary to *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). That contention is flawed for multiple reasons.

First, as discussed above, the plain language of the disputed terms is not sufficiently precise to adequately delineate the scope of the claims. In such instances, the Court must consult the written description and prosecution history to aid in its construction of the terms. *See SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 893-94 (Fed. Cir. 2004); *Datamize*, 417 F.3d at 1350-55. That is precisely what Warner Chilcott advocates here: looking to the specification and prosecution history for an "objective standard" to measure the scope of the otherwise vague, subjective, imprecise claim terms. *Datamize*, 417 F.3d at 1350-55. As discussed above, that "objective standard" is the prior art.

Second, even if the plain language of the disputed terms had a broader, commonly understood ordinary meaning, the applicants disavowed such broader meaning in prosecuting the patent. *See, e.g., Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374-75 (Fed.

Cir. 2008); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002). As discussed above, to overcome an obviousness rejection, the applicants amended their claims and pronounced that the "high contraceptive reliability," "low incidence of follicular development," "satisfactory cycle control," and "reliable avoidance of intracyclic menstrual bleeding and undesirable side effects" distinguished their oral contraceptive from the prior art, and that their regimen provided these characteristics in a low dose regimen "for the first time." Warner Chilcott Opening Brief (D.I. 62) at 5-6. Given such representations, the disputed terms must be construed to make clear that the prior art discussed in the specification of the '940 patent lacked these characteristics, and Bayer cannot recapture through claim construction claim scope that it clearly and unmistakably disclaimed during prosecution. *See, e.g., Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005); *Seachange Intern., Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1364 (Fed. Cir. 2005).

In an attempt to escape the consequences of these representations, Bayer argues that the claims should not be construed to require that the claimed regimen outperform the prior art in each characteristic mentioned in the whereby clause. D.I. 61 (Bayer Br.) at 8-13. Bayer essentially contends that because the Patent Office should not have believed the applicants' statements that their regimen outperformed the prior art in each of the ways that they said it did – and because its claims would be invalid for lack of enablement if those representations are given effect – the Court should decline to give such representations effect. D.I. 61 (Bayer Br.) at 9-10 (arguing that the Examiner should have known that what the applicants said in their patent and told the Patent Office was not possible). But Bayer cannot be excused from the consequences of its representations simply because those statements will now make proving infringement difficult or create invalidity problems for Bayer. *See, e.g., Computer Docking*, 519 F.3d at 1374-75; *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004); *Datamize*, 417 F.3d at 1355. Furthermore, Bayer's contention that Warner Chilcott's constructions should be avoided

because they would render the claims of the '940 patent invalid overlooks the fact that *Bayer's* constructions, if adopted, would render the claims invalid.[4]

Bayer also argues that the intrinsic evidence does not make clear that the '940 patent regimen must be superior to the prior art in *each* of the characteristics contained in the whereby clause, and that the claims should therefore not be construed to require such performance. D.I. 61 (Bayer Br.) at 9-10. But in overcoming the obviousness rejection, the applicants did not state that the '940 patent outperformed the prior art in only *one* respect, or *a few* respects. Jan. 20, 1999 Amendment at 5. Rather, they said that their regimen outperformed the prior art in *several respects*, which is why they amended the claims to add *several* terms reflecting the "superior results" of their regimen. Jan. 20, 1999 Amendment at 1-2, 5. And any possible question about whether the inventors took the position that their regimen outperformed the prior art in *each* characteristic of the whereby clause is resolved by column 6 of the '940 patent, which lists *six* distinct "advantages" of the invented regimen "compared the previously described preparations," without limiting the superiority of the claimed regimen to only *some* of the six characteristics, or only *some* of the prior art regimens.[5] '940 patent col. 6, ll. 9-39.

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[4] Remarkably, Bayer includes excerpts from Warner Chilcott's invalidity contentions, citing them favorably and apparently conceding that Bayer's '940 patent is invalid for lack of enablement under Warner Chilcott's constructions. D.I. 61 (Bayer Br.) at 9-10. But Bayer omits other excerpts from Warner Chilcott's invalidity contentions explaining that if Warner Chilcott's constructions are not adopted, the '940 patent claims would be invalid as indefinite.

[5] Bayer also suggests that a POSA would not have believed that the invented regimen would outperform the prior art in terms of cycle control because these regimens supposedly had higher estrogen doses. D.I. 61 (Bayer Br.) at 9-10. But the applicants stated that their invented regimen, with as little as 15 µg EE in the combination phase tablets, "improved cycle control" even as compared to those regimens containing 30 µg EE or more – indeed, this was a key point of patentability. '940 patent at 6:9-14, 33-39; Jan. 20, 1999 Amendment at 5. Bayer cannot now run from the very representations the inventors made in the '940 patent. Moreover, contrary to what Bayer now argues, many of the prior art regimens cited in the '940 patent specification and prosecution history, including the Pasquale '843 patent, cannot be distinguished on the basis of estrogen dose, as those other patents described use of estrogen doses that overlap with the estrogen doses of the '940 patent. *See, e.g.*, '843 Patent, 3:50-53, 4:7-9,8:4-8 (describing "low (continued…)

Furthermore, if the claimed regimen did not need to outperform the prior art in terms of each characteristic, then the sole objective measure by which to assess the meaning of the subjective, relative words in the disputed claim terms would be gone, rendering the claims indefinite. For example, if an oral contraceptive did not need to outperform the prior art in terms of contraceptive reliability, it would be unclear how reliable the contraceptive needed to be to have "high" contraceptive reliability. But *each* of these effects claimed in the whereby clause must be given meaning, and *each* must be objectively measurable. *See Datamize*, 417 F.3d at 1355.

II. Bayer's Construction of "Effective Estrogen Content" Is Erroneous

Bayer's proposed construction of "effective estrogen content" is flawed for multiple reasons. *First*, Bayer's construction renders the word "effective" superfluous, in violation of settled rules of claim construction. *See Datamize* at 1355 (citing *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1582 (Fed. Cir. 1996)). Claim 1 requires that the oral contraceptive have a "*low* effective estrogen content." '940 patent at 7:36. The requirement that the estrogen content be "low" provides the *upper limit* on the estrogen dose in the claim; "effective" therefore must mean something different. But under Bayer's construction, in which "effective" *also serves* as an upper limit on dose, there would be no difference between a "low estrogen content" and a "low effective estrogen content."

Second, Bayer's construction is inconsistent with the specification, which makes clear that the word "effective" refers to a lower limit on estrogen dose, not an upper limit. *See* '940 patent, 2:60-3:17 (lowering estrogen below 20 µg EE jeopardizes contraceptive efficacy). By

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dose" oral contraceptive with preferred estrogen dose as low as 10 µg EE, and claiming oral contraceptive with "effective" estrogen content); '023 Patent, 6:15-54 (describing embodiment with 20 µg EE, which the '940 patent calls a "very low" estrogen dose at col. 2:61-65).

contrast, the ’940 patent provides no indication that increasing estrogen could undermine effectiveness. *Id.*

Third, Bayer’s contention overlooks the patent’s objective of providing a daily estrogen dose that is “as low as possible.” Warner Chilcott Opening Brief (D.I. 62) at 16-19. Given that objective, the inventors would have preferred a dose lower than 15 µg EE in the combination tablets if doses lower than 15 µg EE were “effective.” *Id.*

Finally, Bayer is wrong that Warner Chilcott’s construction would eliminate the differentiation between claims. D.I. 61 (Bayer Br.) at 6. Claim 1 would not be redundant of claim 3, because claim 3 sets an upper limit of 25 µg EE, while claim 1 does not. ’940 patent at 7:9-40, 7:63-8:14. And claim 1 covers a broader class of estrogens and progestins than claims 2 through 5, is not limited to 28-day regimens as claim 6 is, and is not a method claim, as are claims 7 through 9. ’940 patent at 7:9-8:60. Claims 1 and 10 use different language, giving rise to a presumption of differentiation; to the extent claims 1 and 10 cannot be differentiated, that has nothing to do with Warner Chilcott’s construction of “effective.”

III. The Court Should Adopt Warner Chilcott’s Construction of “Between These Two Hormone Components”

Bayer contends that this term should be given its plain and ordinary meaning, but the fact that Bayer is unwilling to agree to Warner Chilcott’s construction – which gives effect to that plain and ordinary meaning (D.I. 62 at 19-20) – provides reason to doubt Bayer’s assertion. So do Bayer’s infringement allegations, in which Bayer has asserted that the accused Lo Loestrin product literally infringes the claims of the ’940 patent (D.I. 5 at ¶ 24), even though Lo Loestrin undisputedly does not place in a single packaging unit placebo tablets “between” a first hormone component containing a combination of estrogen and progestin tablets, and a second hormone component containing only estrogen (or, as Bayer quibbles, a second hormone component “consisting essentially of an estrogen preparation”).

Bayer's contention that the composition of the "second hormone component" is a component "consisting essentially of an estrogen preparation," rather than only estrogen, is a distinction without a difference. D.I. 61 (Bayer Br.) at 4. The '940 patent states that in the "second" hormone component (which the '940 patent also refers to as a second hormone "phase") "***an*** estrogen is administered" ('940 patent at 3:59-62), and further specifies the dosage units of this second hormone component "***contain only one estrogenic component*** as a hormonal active ingredient." *Id.*, 4:30-32 (emphases added). Bayer itself refers to the second hormone component as "estrogen-only pills" or "unopposed estrogen pills" in its brief. *See* D.I. 61 (Bayer Br.) at 5. And nowhere does the specification suggest that this second hormone component consists of any hormone beyond a single estrogen. Bayer's quibble about the content of the "second hormone" component thus provides no basis for rejecting Warner Chilcott's construction.

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